UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/875,685	12/29/97	LUKAS-LASKEY M	P1614-7038

HM42/0615

NIKAIDO MARMELSTEIN ET AL.
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EXAMINER	
SPIVACK,P	
ART UNIT	**PAPER NUMBER**
1614	7

DATE MAILED: 06/15/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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08/875,603	12/29/97	LUKAS LASKEY	

NIKAIDO MARMELSTEIN ET AL.
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WASHINGTON DC 20005-5701

EXAMINER	
ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 06/08/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-41 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 1-14 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 15-41 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☑ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☑ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Applicants' Preliminary Amendment, Paper No. 5, filed August 4, 1997, is acknowledged. Claims 1-14 are canceled. New claims 15-41 are presented and represent all of the claims presently under consideration.

An Information Disclosure Statement, Paper No. 6, filed December 29, 1997, is further acknowledged and has been reviewed.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over McTavish et al., Drugs.

McTavish teaches the oral administration of a compound of formula I, carvedilol, for its cardioprotective effects in methods of treating congestive heart failure subsequent to, or along with, myocardial infarction, hypertension, coronary artery disease and idiopathic dilated cardiomyopathy. Carvedilol exhibits β-adrenoceptor antagonism and causes peripheral vasodilation primarily via a_1-adrenergic blockade. A combination with at least one other therapeutic agent, as for example, hydrochlorothiazide, atenolol or nicardipine, is disclosed on

page 249. Various dosages or timing sequences of administration are disclosed on page 252-253. The reference fails to disclose a unit dosage formulation specifically comprising 1.0-10.0mg carvedilol and pharmaceutical formulations, including a kit, comprising the combination of a compound that is a β-adrenoreceptor antagonist and an a_1-adrenoreceptor antagonist, along with at least one other therapeutic agent selected from the group consisting of angiotensin converting enzyme inhibitors, diuretics and cardiac glycosides. However, one having ordinary skill in the art would have been motivated to prepare various dosages and dosage forms, and to modify the sequence of drug administration, in view of the teaching of McTavish. Such modification would have been obvious in the absence of evidence to the contrary because the skilled artisan in formulation chemistry would have reasonably sought the most efficacious dosage and dosing regimen to insure a nontoxic and effective blood level of carvedilol with due regard for the stability of the preparation. Packaging in the form of a kit is conventional. It would have been reasonable to expect a treatment for congestive heart failure to lead ultimately to a method of treatment to decrease mortality.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phyllis Spivack whose telephone number is (703) 308-4703.

Spivack/sg

June 9, 1998

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER